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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,506	05/01/2001	William A. O'Brien	026.00231	5515

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EXAMINER
SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

F-6

Office Action Summary	Application No. 09/846,506	Applicant(s) O'BRIEN ET AL.	
	Examin r J. Douglas Schultz	Art Unit 1635	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application/Amendment/Claims

1. Applicant's response filed February 24, 2003 has been considered. Applicant's amendment of claim 5 has been fully entered. Rejections and/or objections not reiterated from the previous office action mailed August 13, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-10 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the same reasons of record as set forth August 13, 2002.

Applicants' argue that the present specification provides adequate disclosure of the genus of CD63 inhibitors such that one of skill would be able to recognize that applicants had possession of the genus of CD63 inhibitors for use in the instantly claimed methods. Applicants argue that although only one inhibitor of CD63 has been disclosed for use in the presently

claimed method, that the screening method on page 12 lines 1-14 would provide one of skill in the art with the ability to find other suitable inhibitors.

This argument is not considered convincing. Applicants disclosure of a single inhibitor molecule does not reasonably constitute a representative sample of all possible CD63 inhibitors, a genus which includes any antibody, antisense, small organic molecule, ribozyme, peptide/aptamer, or dominant negative mutant that inhibits CD63 function. Applicants appear to acknowledge that one antibody inhibitor does not provide adequate disclosure, by arguing that the screening method set forth in the specification provides sufficient additional support to possess the use of the genus of CD63 inhibitors. However, applicants' screening process is not considered sufficient description of a representative sample of any CD63 inhibitor as required by the Guidelines on Written Description and discussed in the previous Office action. Applicants' admission that one of skill would have to screen for inhibitors to use in the present invention is indicative of the lack of written description plaguing the instant claims. A patent is not a hunting license, and one of skill would necessarily have to undergo a drug discovery process as outlined by applicants in order to identify the other members of the broad genus embracing the claimed invention.

Furthermore, the inhibitor screening process itself is fundamentally compromised by the fact that the function of CD63 is apparently unknown. Since claim 2 specifically recites an inhibitor of the functional CD63, the claimed compounds must therefore have the property of inhibiting functional CD63. Thus, it appears on its face that one of skill would need to know the function of CD63 before attempting to screen for inhibitors of CD63. This issue was raised in the previous Office action, to which applicants have responded, "'functional' expression refers to the

synthesis and any necessary post-translational processing of a CD63 molecule in a cell so that the CD63 is active". However, neither applicants' arguments nor the specification as filed describe the function of an "active" CD63. Accordingly, the failure to disclose a known function of CD63 has problematic implications when one is trying screen for inhibitors of the heretofore undescribed function. For these reasons the rejection of the above claims for lacking written description is maintained.

4. Claims 1-10 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *in vitro* method whereby HIV entry into macrophages expressing co-receptor CCR5 alone is inhibited by CD63 antibodies alone, and for an *in vitro* method whereby HIV entry into macrophages expressing both co-receptors CCR5 and CXCR4 is inhibited by CD63 antibodies in combination with a CXCR4 inhibitor, does not reasonably provide enablement for any *in vivo* inhibition of HIV cell entry or treatment or prevention of disease comprising modulation of CD63 levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the same reasons of record as set forth in the Office action mailed August 13, 2002.

Applicants argue that the specification needs only to disclose a method that bears reasonable correlation to the entire scope of the claims in order to be enabled. Applicants further argue that in considering enablement, the PTO must consider whether one of skill in the art could practice the invention without undue experimentation. Applicants assert that the present

specification sets forth methods that provide full enablement, for both *in vitro* and *in vivo* practice of the instant invention.

These arguments are not considered convincing. Applicants have demonstrated an *in vitro* method whereby HIV entry into macrophages expressing co-receptor CCR5 alone is inhibited by CD63 antibodies alone, and an *in vitro* method whereby HIV entry into macrophages expressing both co-receptors CCR5 and CXCR4 is inhibited by CD63 antibodies in combination with a CXCR4 inhibitor. In contrast, the claims are drawn to the reduction of HIV entry into cells by reducing the amount of functional CD63, said claims encompassing *in vivo* treatment. As presented in the references of the previous Office action, *in vitro* model systems do not correlate well with the *in vivo* environment, primarily due to problems with immune response and target access in the whole animal. These references discuss specific art-recognized problems that form the basis for the instant enablement rejection, problems that cannot be addressed in cell culture systems. These issues have gone unconsidered in applicants' response. Accordingly, applicants *in vitro* model system and prophetic guidance is not considered to bear a reasonable correlation to the *in vivo* inhibition of HIV cell entry or treatment of disease comprising modulation of CD63 levels. Moreover, applicants have provided no evidence or reasoning to rebut the multiple cited references provided in the previous Office action, other than the assertions above. As a result of the lack of correlation of applicants' model system and the unresolved issues in the prior art in regards to the use of antibody and nucleic acid inhibitors in the *in vivo* environment, one of skill in the art would have to engage in undue experimentation in order to practice the invention as claimed.

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
May 9, 2003

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600